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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/741,929	12/19/2003	Clarence Nathaniel Ahlem	202.2D6	4810
26551	7590	01/12/2006	EXAMINER	
HOLLIS-EDEN PHARMACEUTICALS, INC.			BADIO, BARBARA P	
4435 EASTGATE MALL			ART UNIT	PAPER NUMBER
SUITE 400			1617	
SAN DIEGO, CA 92121			DATE MAILED: 01/12/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/741,929	AHLEM ET AL.
	Examiner	Art Unit
	Barbara P. Badio, Ph.D.	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 32-37 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/05, 7/05, 10/05.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_.

**Non-final Office Action on the Merits**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Status of the Application***

2. Claims 1-10 and 32-37 are pending in the present application. Claims 1-10 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 32-37 will be examined according to MPEP § 803.02.

***Double Patenting***

3. **The provisional rejection of claims 25-28 under the judicially created doctrine of obviousness-type double patenting over claims 1-10, 15-19, 22 and 23 of copending Application No. 10/877,911 is made moot by the cancellation of the instant claims.**

4. Claims 32-37 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 15-19, and 23 of copending Application No. 10/877,911. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass a method of treating osteoporosis utilizing the claimed compounds. Unlike the copending Application, the present Application recites a limited genus of compounds.

However, there is an overlap in the compounds recited by the two inventions. For example, both encompass applicant's elected compound, i.e.,  $3\alpha,17\beta$ -dihydroxy-19-norandrost-4-ene (see claim 37 of the present Application and claim 19, 4<sup>th</sup> compound of the copending Application) and, thus, the utilization of the elected compound in the treatment of osteoporosis would be obvious to the skilled artisan based on the disclosure of the cited copending Application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 32-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/749,981. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications encompass the treatment of osteoporosis by administering a composition comprising androst-5-ene- $3\beta,17\beta$ -diol. Unlike the copending application, the instant claims recite a broader genus of compounds and is limited to treatment of osteoporosis. However, the selection of androst-5-ene- $3\beta,17\beta$ -diol from the genus taught by the present application would be obvious based on the disclosure of the corresponding androst-5-ene- $3\alpha,17\beta$ -diol as recited by claim 36 of the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

**6. The rejection of claims 25-28 under 35 USC 112, first paragraph is made moot by the cancellation of the instant claims.**

**7. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**8. Claims 32-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

The instant claims are indefinite for the following reasons:

(a) claim 32 recites but does not identify "R<sup>13</sup>" and (b) claim 34 recites the limitation "R<sup>9</sup> is -O-" or "R<sup>9</sup> is -NH-" in (18) and (19) and there is insufficient antecedent basis for this limitation in the claim.

***Claim Objections***

**9. The objection of claims 25-28 under 37 CFR 1.75(c) is made moot by the cancellation of the instant claims.**

**10. Claim 36 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.**

Claim 36 recites compounds such as  $3\alpha,17\beta$ -dihydroxyandrost-4-ene and  $3\alpha,17\beta$ -dihydroxyandrost-5-ene not encompassed by the parent claim. Parent claim 35 is limited to 19-nor steroid derivatives.

***Claim Rejections - 35 USC § 102***

**11. The rejection of claims 25-28 under 35 USC 102(b) over Kousteni et al. is withdrawn.**

12. Claims 32, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Labrie (US 6,432,940).

Labrie teaches the utilization of androst-5-en-3 $\beta$ ,17 $\beta$ -diol in the treatment of osteoporosis (see the entire article, especially Abstract; col. 2, lines 35-41). The method of use taught by the reference is encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

**13. The rejection of claims 25-28 under 35 USC 103(a) over Kousteni et al. is withdrawn.**

14. Claims 32-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Labrie (US 6,432,940).

Labrie teaches the utilization of androst-5-en-3 $\beta$ ,17 $\beta$ -diol in the treatment of osteoporosis (see the entire article, especially Abstract; col. 2, lines 35-41).

The instant claims encompass the 3 $\alpha$ -isomer of the prior art compound. However, the court has held that a compound that is isomeric with the prior art compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound. *In re Norris*, 179 F.2d 970, 84 USPQ 458 (CCPA 1970). Based on the decision by the court, the instantly claimed invention is not patentable over the cited prior art.

***Other Matters***

15. Applicant's statement that filing of a terminal disclaimer at this time is premature is noted.

***Telephone Inquiry***

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Radio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
January 10, 2006